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concentrations for drug residues in edible swine tissue.

**EFFECTIVE DATE:** July 29, 1986.

**FOR FURTHER INFORMATION CONTACT:** Adriano R. Gabuten, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-433-4913.

**SUPPLEMENTARY INFORMATION:** Merck Sharp & Dohme Research Laboratories, Division of Merck & Co., Inc., P.O. Box 2000, Rahway, NJ 07065, filed NADA 135-008 providing for subcutaneous use of IVOMEC\* (ivermectin) injection in swine for treating and controlling infections caused by certain species of gastrointestinal roundworms, lungworms, lice, and mites. The drug is currently approved for intramuscular use in horses and subcutaneous use in cattle and in reindeer (21 CFR 522.1192).

The NADA is approved. The regulations are amended to reflect the approval and to establish a tolerance for the marker residue and safe concentrations for total residues of ivermectin in edible swine tissue. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(iii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. FDA's regulations implementing the National Environmental Policy Act (21 CFR Part 25) have been replaced by a rule published in the Federal Register of April 28, 1985 (50 FR 18636, effective July 25, 1985). Under the new rule, an action of this type would require an environmental assessment under 21 CFR 25.31a(a).

#### List of Subjects

##### 21 CFR Part 522

Animal drugs.

##### 21 CFR Part 556

Animal drugs; Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, Parts 522 and 556 are amended as follows:

#### PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR Part 522 continues to read as follows:

Authority: Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)); 21 CFR 5.10 and 5.83.

2. In § 522.1192 by revising the heading of paragraph (a)(2) and adding new paragraph (d)(4) to read as follows:

##### § 522.1192 Ivermectin injection.

(a) . . .

(2) Cattle, reindeer, and swine. . . .

(d) . . .

(4) Swine—(i) Amount. 10 milligrams (1 milliliter) per 75 pounds of body weight.

(ii) Indications for use. It is used in swine for treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (*Ascaris suum*, *Hyostrongylus rubidus*, *Oesophagostomum* spp., *Strongyloides ransomi* (adults only)); lungworms (*Metastrongylus* spp. (adults only)); lice (*Haematopinus suis*); and mites (*Sarcoptes scabiei* var. *suis*).

(iii) Limitations. For subcutaneous injection in the neck of swine only. Do not treat swine within 18 days of slaughter. Do not use in other animal species as severe adverse reactions, including fatalities in dogs, may result. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

#### PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR Part 556 continues to read as follows:

Authority: Sec. 512, 82 Stat. 343-351 (21 U.S.C. 360b); 21 CFR 5.10 and 5.83.

4. By revising § 556.344 to read as follows:

##### § 556.344 Ivermectin.

The marker residue tolerance and safe concentrations for total residues in edible tissues of target animals are as follows:

(a) Cattle and reindeer. The marker residue used to monitor the total residues of ivermectin in cattle and reindeer is 22,23-dihydro-avermectin B<sub>1a</sub>. The target tissue selected in liver. A tolerance is established for 22, 23-dihydro-avermectin B<sub>1a</sub> in cattle and reindeer of 15 parts per billion in liver. A marker residue concentration of 15 parts per billion in liver corresponds to a concentration for total residues of ivermectin of 50 parts per billion in liver. The safe concentrations for total residues of ivermectin in uncooked edible tissues of cattle and reindeer are 25 parts per billion in muscle, 50 parts per billion in liver, 75 parts per billion in kidney, and 100 parts per billion in fat.

(b) Swine. The marker residue used to monitor the total residues of ivermectin in swine 22,23-dihydro-avermectin B<sub>1a</sub>. The target tissue selected is liver. A tolerance is established for 22,23-dihydro-avermectin B<sub>1a</sub> in swine of 20 parts per billion in liver. A marker residue concentration of 20 parts per billion in liver corresponds to a concentration for total residues of ivermectin of 75 parts per billion in liver. The safe concentrations for total residues of ivermectin in uncooked edible tissues of swine are 25 parts per billion in muscle, 75 parts per billion in liver, 100 parts per billion in kidney, and 100 parts per billion in fat.

Dated: July 22, 1986.

Richard H. Teske,  
Acting Director, Center for Veterinary Medicine.

[FR Doc. 86-16838 Filed 7-28-86; 8:45 am]

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#### DEPARTMENT OF JUSTICE

##### 28 CFR Part 50

[Order No. 1139-86]

#### Statement of Policy Concerning Indemnification of Department of Justice Employees

**AGENCY:** Department of Justice.

**ACTION:** Statement of policy.

**SUMMARY:** Existing Department policy precludes the payment of Department funds to indemnify Department employees who suffer adverse money judgments as a result of official acts, or the settlement of personal damages claims by the payment of Department funds. This amendment announces a change in policy to permit such payment in appropriate cases, as determined by the Attorney General.

**EFFECTIVE DATE:** July 29, 1986.

**FOR FURTHER INFORMATION CONTACT:** Gregory S. Walden, Associate Deputy Attorney General, Department of Justice, Room 4119, Main Building, Washington, DC 20530; (202) 633-2268.

**SUPPLEMENTARY INFORMATION:** Unlike most state and local governments and general corporate practice, the Department of Justice does not now indemnify its employees who are sued personally and suffer an adverse judgment as a result of conduct taken within the scope of employment, nor does it settle individual capacity claims with Department funds. Lawsuits against federal employees in their individual capacity have proliferated since the 1971 Supreme Court decision in *Bivens v. Six Unknown Named Agents of the Federal Bureau of Narcotics*, 403 U.S. 388. In this brief time over 12,000 claims have been filed against federal employees personally; nearly 3,000 are pending today. These suits personally attack officials at all levels of government and target all federal activities, particularly law enforcement. Although the federal workforce is on the whole exceptionally well-disciplined—the Department is aware of only 32 adverse judgments against individual federal employees—the risk of personal liability and the burden of defending a suit for money damages, simply a result of doing one's job, are real enough in many cases.

It is obvious that an adverse judgment has detrimental consequences for the federal employee, both pecuniary and otherwise. Of greater consequence to the federal government, however, is the fear of personal liability, because it is this concern which affects governmental operations, decision making, and policy determinations. The prospect of personal liability, and even the uncertainty as to what conduct may result in a lawsuit against the employee personally, tend to intimidate all employees, impede creativity and stifle initiative and decisive action. As Professor Kenneth Culp Davis has noted, "The public suffers whenever a government employee resolves doubts in order to protect his own pocketbook instead of resolving doubts in order to protect the public interest. . . . Courageous action of public employees is often essential, and it should not be discouraged by the threat of a lawsuit against the employee personally." K. Davis, *Constitutional Torts* at 25, 26 (1984).

The Department believes that lawsuits against federal employees in their personal capacity now constitute a major impediment to the effective

conduct of the public's business and enforcement of the law. A change in Department policy to permit the indemnification of Department employees would go a long way toward removing this impediment, and would accord Department employees the same protection now enjoyed by most state and local government employees as well as employees of most corporate employers.

This change in policy permits, but does not require, the Department to indemnify a Department employee who suffers an adverse verdict, judgment, or other monetary award provided that the actions giving rise to the judgment were taken within the scope of employment and that such indemnification is in the interest of the United States, as determined by the Attorney General. The criteria for payment are substantially similar to the criteria used to determine whether a federal employee is entitled to Department of Justice representation under 28 CFR 50.15(a).

The policy also allows the Department in rare cases to settle an individual capacity claim by the payment of Department funds, upon a similar determination by the Attorney General. Absent exceptional circumstances, the Department will not agree either to indemnify or settle before entry of an adverse judgment. The change in policy is thus designed to discourage the filing of lawsuits against federal employees in their individual capacity solely in order to pressure the government into settlement. In the usual case, the denial of dispositive motions or the delay in deciding them will not lead to settlement before trial and judgment.

The policy will not have a significant economic impact on substantial number of small entities within the meaning of 5 U.S.C. 605(b).

#### List of Subjects in 28 CFR Part 50

Administrative practice and procedure, Government employees, Employment, Tort claims.

By virtue of the authority vested in me by 28 U.S.C. 509 and 510 and 5 U.S.C. 301, Part 50 of Title 28 of the Code of Federal Regulations is amended as follows:

#### PART 50—[AMENDED]

1. The authority citation for Part 50 is revised to read as follows:

Authority: 28 U.S.C. 508, 509, 510, 516, 517, 518, 519; 5 U.S.C. 301, 552, and 552a; 15 U.S.C. 16(d); E.O. 11247; 3 CFR (1964-65 Comp.) 348.

2. Section 50.15(a)(7)(iii) is amended by adding the following phrase, after the semicolon, to read as follows:

#### § 50.15 [Amended]

(a) . . .

(7) . . .

(iii) . . . but that, where authorized, the employee may apply for such indemnification from his employing agency upon the entry of an adverse verdict, judgment, or other monetary award;

Section 50.15 is amended by adding a new paragraph (c) to read as follows:

#### § 50.15 [Amended]

(c)(1) The Department of Justice may indemnify the defendant Department of Justice employee for any verdict, judgment, or other monetary award which is rendered against such employee, provided that the conduct giving rise to the verdict, judgment, or award was taken within the scope of employment and that such indemnification is in the interest of the United States, as determined by the Attorney General or his designee.

(2) The Department of Justice may settle or compromise a personal damages claim against a Department of Justice employee by the payment of available funds, at any time, provided the alleged conduct giving rise to the personal damages claim was taken within the scope of employment and that such settlement or compromise is in the interest of the United States, as determined by the Attorney General or his designee.

(3) Absent exceptional circumstances as determined by the Attorney General or his designee, the Department will not entertain a request either to agree to indemnify or to settle a personal damages claim before entry of an adverse verdict, judgment, or award.

(4) The Department of Justice employee may request indemnification to satisfy a verdict, judgment, or award entered against the employee. The employee shall submit a written request, with appropriate documentation including copies of the verdict, judgment, award, or settlement proposal if on appeal, to the head of his employing component, who shall thereupon submit to the appropriate Assistant Attorney General, in a timely manner, a recommended disposition of the request. Where appropriate, the Assistant Attorney General shall seek the views of the United States Attorney; in all such cases the Civil Division shall be consulted. The Assistant Attorney General shall forward the request, the employing component's recommendation, and the Assistant

Attorney General's recommendation to the Attorney General for decision.

(5) Any payment under this section either to indemnify a Department of Justice employee or to settle a personal damages claim shall be contingent upon the availability of appropriated funds of the employing component of the Department of Justice.

Dated: June 21, 1986.

Edwin Meese III,

Attorney General.

[FR Doc. 86-16925 Filed 7-28-86; 8 45 am]

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## DEPARTMENT OF LABOR

### Occupational Safety and Health Administration

#### 29 CFR Part 1952

#### Approved State Plans for Enforcement of State Standards; Approval of Supplements to the Oregon State Plan; Notice of Amendment to the Level of Federal Enforcement

**AGENCY:** Occupational Safety and Health Administration (OSHA), Labor.

**ACTION:** Approval of Supplements to the Oregon State Plan; Notice of Amendment to the Level of Federal Enforcement.

**SUMMARY:** This document gives notice of approval of State plan supplements including a revised Oregon field compliance manual, an industrial hygiene technical manual, an inspection scheduling system, amendments to administrative regulations, and State-initiated changes associated with administrative reorganization, compliance procedures and agreements with other agencies. This document also gives notice of an amendment to the operational status agreement which reflects a change in the level of Federal enforcement in the State.

**EFFECTIVE DATE:** July 29, 1986.

**FOR FURTHER INFORMATION CONTACT:** James Foster, Director, Office of Consumer Affairs, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 (202) 523-8148.

#### SUPPLEMENTARY INFORMATION:

##### Background

The Oregon Occupational Safety and Health Plan was approved under section 18(c) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 667(c)) (hereinafter referred to as the Act) and Part 1953 of this chapter provides

procedures for the review and approval of State plan change supplements and agreements recognizing the level of Federal enforcement within a State plan by the Assistant Secretary of Labor for Occupational Safety and Health (hereinafter referred to as the Assistant Secretary).

#### Description of Supplements

##### A. Oregon Field Compliance Manual

The State submitted a revised manual on March 7, 1984, with subsequent revisions on April 17, 1984, January 3, 1985, May 17, 1985, and October 16, 1985, respectively, which details compliance procedures for its occupational safety program. The manual is modeled generally after the Federal manual, and revisions thereto through February 11, 1985.

##### B. Oregon Industrial Hygiene Technical Manual

The State submitted its manual detailing industrial hygiene technical procedures on January 15, 1985. The State manual is modeled after the Federal manual as issued March 30, 1984.

##### C. Inspection Scheduling System

The State submitted a supplement providing its safety and health inspection scheduling system on December 30, 1982, consistent with its rules governing inspection scheduling which were approved in the Federal Register on September 24, 1982 (47 FR 42108). Inspections are programmed using lists of employers which have a high incidence of workers compensation claims, whose operations are within industries with high injury rates, or which have a high potential for health problems. The State also submitted a supplement on December 8, 1983, providing acceptable program planning goals as a response to those issued Federally on October 31, 1983.

##### D. Amendments of Legislation

On July 27, 1983, the State submitted amendments to the Oregon Safe Employment Act, its enabling legislation, to replace gender specific pronouns with gender neutral language and to substitute synonymous language in the section prohibiting discrimination against employees who exercise their rights under the legislation. The amendments made no substantive changes.

##### E. Guidelines for Superfund and Other Hazardous Waste Sites

The State submitted a supplement on June 17, 1984, advising that it would not provide coverage of private sector

employees at Superfund waste sites and acknowledging responsibility to protect State and local public sector employees at such sites. The State does cover both private and public sector employees at other toxic waste dumps not designated as Superfund sites. The State supplement responded to Federal policy issued December 30, 1983.

##### F. Policy on MSHA/OSHA Jurisdiction

The State submitted procedures effective May 18, 1981, to ensure consistency with OSHA policy issued March 14, 1980, providing guidance on determining enforcement responsibility in situations where the Mine Safety and Health Administration's and OSHA's jurisdiction overlapped. The policy resulted from an MSHA/OSHA jurisdictional agreement.

##### G. Regulations Concerning Personal Sampling

The State submitted an amendment to its regulations (436-46-015 and 090) on July 22, 1983, closely comparable to Federal changes to regulations at 29 CFR 1903.7, effective January 10, 1983, which provided authority for use of personal sampling devices during inspections.

##### H. Petitions for Modification of Correction Period

The State submitted an amendment to its regulations (436-46-251), effective February 1, 1983, which places the burden of proof on an employer at hearings on petitions to modify correction, provides procedures for reconsideration of a denied petition under certain conditions subsequent to decisions by the review board, and clarifies posting requirements to ensure employee notification of such reconsiderations. The amendment implemented assurances made as a condition for approval of the State administrative regulations as a completed developmental step on September 24, 1982 (47 FR 42108).

##### I. Repeat Violations

The State submitted an amendment to its regulations (436-46-015 and 145) effective November 1, 1984, which sets a 3 year limit on repeat violations (consistent with Federal policy), and which precludes penalty adjustments for repeat violations contributing to actual employee injury, illness or death.

##### J. Recordkeeping

Oregon submitted amendments to its regulations effective March 15, 1984 (436-46-015, 052, 701, and 725), reflecting Federal regulations at 29 CFR 1904.12, providing exemption from recordkeeping